

SIMPLE PLEASURES ANTIBACTERIAL FOAMING HAND- triclosan soap
Tri-Coastal Design Company Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredient

Triclosan 0.3%

Purpose

Antiseptic

Uses

- For handwashing to decrease bacteria on the skin
- Recommended for repeated use

Warnings

- For external use only
- Flammable, keep away from fire and flame
- Does not contain grain alcohol; do not drink.

If taken internally will produce serious gastric disturbances

When using this product

- Avoid the eyes and mucous membranes
- In the case of eye or mucous membrane contact; rinse area thoroughly with water

Stop use and ask a doctor if

- condition worsens
- redness or irritation develops
- condition persists for more than 3 days

Keep out of reach of children

If swallowed contact a doctor or Poison Control Center immediately.

Directions

- Wet hands, work into a lather. Rinse well
- Supervise children in the use of this product
- In the case of eye contact, rinse eyes thoroughly with water

Other information

- Store below 105F
- May discolor some fabrics

Inactive Ingredients

Benzophenone-4, Citric Acid, Cocamidopropyl Betaine, Cocamide DEA, Disodium EDTA, FDC Blue 1, FDC Yellow 5, Fragrance (Parfum), Methylchloroisothiazolinone, Methylisothiazolinone, PEG-150 Distearate, Sodium Laureth Sulfate, Water (Aqua)

Package Label

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 www.tricoastaldesign.com
 Designed in the USA. Made in China
 8.1 fl oz / 240 ml

SIMPLE PLEASURES ANTIBACTERIAL FOAMING HAND

triclosan soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49852-173
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM50 39 Y5X) (TRICLOSAN - UNII:4NM50 39 Y5X)	TRICLOSAN	0.3 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BENZOPHENONE (UNII: 701M4TTV9O)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49852-173-08	240 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/21/2012	

Labeler - Tri-Coastal Design Company Inc. (609734900)

Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou St Eva Fine Chemical Co Ltd		528039793	manufacture(49852-173)

Revised: 10/2012

Tri-Coastal Design Company Inc.